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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,658	01/16/2004	Marc Elliot Rothenberg	CMC -162	8032

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EXAMINER	
BUNNER, BRIDGET E	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/759,658	ROTHENBERG, MARC ELLIOT	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, 16-32, drawn to a method to mitigate an allergic response comprising administering an inhibitor, classified in class 514, subclass 2.

II. Claims 7-10, drawn to a pharmaceutical composition comprising an inhibitor, classified in class 424, subclass 185.1.

III. Claims 11-15, drawn to a physiological assessment method comprising determining a level of at least one of resistin-like molecule α or resistin-like molecule β in a patient, classified in class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

a. Inventions I and III are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). Groups I and III are different methods requiring different methods steps, wherein each is not required, one for another. For example, Invention I requires search and consideration of administration of an inhibitor of a RELM molecule, which is not required by the other invention. Invention III requires search and consideration of determining a level of a RELM molecule in a patient, which is not required by the other invention.

Furthermore, the distinct steps and products require separate, distinct, and non-overlapping coextensive searches. As such, it would be burdensome to search the inventions of Groups I and III together.

b. Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the RELM inhibitor of group II can be used in other materially different assays, such as *in vitro* cell assays.

Additionally, searching the inventions of Groups II and I together would impose serious search burden. The inventions of II and I have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for a RELM inhibitor and method of use are not coextensive.

c. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions of Groups II and III are unrelated product and method, wherein each is not required, one for another. For example, the RELM inhibitor of Invention II cannot be used together with the claimed method of Invention III because this invention does not recite the use or production of the inhibitor.

2. Because these inventions are independent or distinct for the reasons given above and the inventions have acquired a separate status in the art in view of their different classification and require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

3. **If Applicant elects Invention I or II, one of the following species must also be elected.**

This application contains claims directed to the following patentably distinct species of RELM molecule:

a. inhibitor/regulator of RELMα (expression)

b. inhibitor/regulator of RELMβ (expression)

c. inhibitor of RELMα receptor binding

d. inhibitor of RELMβ receptor binding

e. RELMα

f. RELMβ

The species are independent or distinct because each of the RELM molecules listed as (a)-(f) have different structural and functional characteristics. The species are independent or distinct because each requires separate, non-coextensive searches. For example, a technical literature search for administration of a RELMα inhibitor may not result in relevant art with respect to administration of RELMβ.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 7, 16, and 26 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. **If Applicant elects Invention I, one of the following species must also be elected.**

This application contains claims directed to the following patentably distinct species of RELM regulator:

g. IL-4

h. IL-13

i. STAT6

j. small molecule activator of STAT6

k. STAT6 oligonucleotide

l. activator of STAT6 transcription

The species are independent or distinct because each of the RELM inhibitors/regulators listed as (g)-(l) have different structural and functional characteristics. The species are independent or distinct because each requires separate, non-coextensive searches. For example, a technical literature search for administration of IL-4 may not result in relevant art with respect to administration of an activator of STAT6.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 16, and 26 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. **If Applicant elects Invention I, one of the following species must be elected.**

This application contains claims directed to the following patentably distinct species of mitigation of lung disease by reduction of:

m. leukocyte accumulation

n. mucus production

o. cell proliferation

p. collagen deposition

q. macrophage accumulation

r. fibroblast accumulation

s. acid secretion

The species are independent or distinct because each of the reductions listed as (m)-(s) are different physiological responses that require separate, non-coextensive searches. For example, a technical literature search for a reduction of leukocyte accumulation may not result in relevant art with respect to a reduction in acid secretion.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 16 and 26 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. **If Applicant elects Invention II, one of the following species must also be elected.**

This application contains claims directed to the following patentably distinct species of inhibitor of a RELM molecule:

t. inhibitor of STAT6

u. inhibitor of a Th2 cytokine

v. a small molecule inhibitor

w. an oligonucleotide inhibitor

x. a transcriptional inhibitor

y. a translational inhibitor

The species are independent or distinct because each of the inhibitors of a RELM molecule listed as (t)-(y) have different structural and functional characteristics. The species are independent or distinct because each requires separate, non-coextensive searches. For example, a technical literature search for administration of a pharmaceutical composition comprising an inhibitor of STAT6 may not result in relevant art with respect to a pharmaceutical composition comprising a translational inhibitor.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 7 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

7. **If Applicant elects Invention II or III, one of the following species must also be elected.**

This application contains claims directed to the following patentably distinct species of type of RELM inhibition:

z. RELMα DNA

aa. RELMβ DNA

bb. RELMα mRNA

cc. RELMβ mRNA

dd. RELMα protein

ee. RELMβ protein

The species are independent or distinct because each type of RELM inhibition listed as (z)-(ee) refers to structurally and functionally different molecules that require different techniques for detection and measurement. The species are independent or distinct because each requires separate, non-coextensive searches. For example, a technical literature search for detecting RELMα DNA may not result in relevant art with respect to detection of RELMβ protein..

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 7 and 11 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. **If Applicant elects Invention III, one of the following species must be elected.**

This application contains claims directed to the following patentably distinct species of patient parameters:

ff. clinical status

gg. phenotype

hh. genotype

ii. drug response

jj. prognosis

kk. single nucleotide polymorphisms

The species are independent or distinct because each of the patient parameters listed as (ff)-(kk) require different techniques for detection and measurement. The species are independent or distinct because each requires separate, non-coextensive searches. For example, a technical literature search for measuring a patient's clinical status may not result in relevant art with respect to measuring a patient's single nucleotide polymorphisms.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 11 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of

the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BEB
Art Unit 1647
07 August 2006

Bridget E. Bunner

BRIDGET BUNNER
PATENT EXAMINER